

From the INTERNATIONAL SEARCHING AUTHORITY

**PCT**

To:

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UNITED STATES OF AMERICA

8195.35US01 - KDS

ATY IDS US PTA: August 14, 2005

ATY IDS DUE: October 15, 2005 B✓

## INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

Pay Fees: August 15, 2005 D✓ klw

Date of mailing  
(day/month/year) 15/07/2005

Applicant's or agent's file reference

8195.35WO01✓

PAYMENT DUE within ONE MONTH from  
the above date of mailing

International application No.

PCT/US2005/009203

International filing date  
(day/month/year) 18/03/2005

Applicant

THE TAPEMARK COMPANY

## 1. This International Searching Authority

- (i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated KLW on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated KLW on the extra sheet:

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

see annex

- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

## 2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 1.550,0 x 1 = EUR 1.550  
Fee per additional invention number of additional inventions total amount of additional fees

Or, \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☐ Claim(s) Nos. \_\_\_\_\_ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority



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Authorized officer

Maria Howarth

## Important information

Rule 40 PCT has been amended as of 1 April 2005. For general information on the protest procedure under the PCT please refer to OJ EPO 3/2005, pages 226/227.

1. As in the past the payment of any additional fee may be made under protest i.e. accompanied by a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fees is excessive according to amended Rule 40.2(c) PCT.
2. Although no longer obligatory, prior to examination of the protest by the Board of Appeal the EPO will subject the invitation to pay additional fees to an internal review which is free of charge. The result of this review will be communicated to the applicant.
3. The fee for examination of the protest (Rule 40.2(e) PCT) is payable within one month of the date of the invitation to pay additional fees (Rule 40.1(iii) PCT), however, in order to allow the applicant to consider the result of the internal review, the applicant may pay the protest fee within one month from the date of notification of the result of the review.
4. Should the applicant wish to maintain his protest in light of the review he must pay the protest fee within one month from the date of notification of the result of the internal review, in which case the protest will be referred to the Board of Appeal. Should the Board of Appeal find that the protest was entirely justified, the protest fee shall be refunded.
5. In the event of the applicant already having paid the protest fee before notification of the result of the review, the protest will be referred to the Board of Appeal **unless** the result of the internal review was that the protest was **entirely** justified **or** the applicant indicates within one month from the date of notification of the result of the review that he does not wish to continue the protest, in both cases the protest fee will be refunded.

# Important Information

## General

- the **claims cannot be changed** at this point in the procedure, the transmitted report is **not** the ISR (see Art. 19 PCT)
- non-payment does not lead to a **loss of rights**, a new procedure will be started on entry into the regional or national phase
- any payments have to be effected **directly** to this ISA (account details on separate sheets), payments to other entities will not be accepted
- in case of a **total of more than 2 inventions** found: when paying please **specify exactly** which claims should be searched
- an **extension of the set time limit** cannot be granted

## Payment by cheque:

- the **date of payment** is considered to be the **date the original cheque is received at the EPO**, under the condition that the cheque is **covered**
- faxed cheques are not considered to be a valid payment
- only payments in EUR are accepted, no equivalents in other currencies

## Payment by money transfer:

- the **date of payment** is considered to be the **date the money is booked** in the EPO bank account
- only payments in EUR are accepted, no equivalents in other currencies

## Payment by deposit account:

- the **date of payment** is considered to be the date that the **authorisation** to deduct fees from the deposit account is **received at the EPO**

***note:** if you don't have a deposit account with the EPO yourself you might want to consider using the account of an associate as a safe and quick way of paying*

## Payment by credit card:

- payments by **credit card** are **not possible**

## Payments under protest according to Rule 40 PCT:

- the protest will **not be accepted without a payment** of additional search fee(s)
- the protest has to be **accompanied by a technical reasoning**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-27

A film containing both HPC and a fatty alcohol  
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2. claims: 28-46

The production of a film by extrusion from a composition containing a water-soluble film former and a fatty alcohol  
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Reference is made to the following document:

D1: WO-A-99 55 312.

Present claims 1-27 (INVENTION I) relate to a film containing hydroxypropyl cellulose and a fatty alcohol.  
Present claims 27-46 (INVENTION II) relate to the extrusion of a film containing a water-soluble film-former and a fatty alcohol.

(b) Document D1 discloses a pharmaceutical carrier comprising a layered film of a total thickness of from 0.1 to 1 mm (see claims 1 and 17). The film forming polymer may be hydroxypropyl cellulose (see claim 16 at 43/25 and examples 2, 3, 25, 31, 32, 34, 35 and 37). The composition may contain a plasticizer, e.g. fatty alcohols, such as cetyl-, myristyl, and stearyl alcohol in order to improve the mechanical properties, to modify the erosion behaviour, the drug release profile or disintegration time (see 14/19-20). In example 20, disks of 0.5 inch of diameter and a thickness between 0.19 to 0.21 mm containing HEC and dyclonine HCl or benzocaine were set in the mouth.

(c) The subject-matter of the present claims differs from the disclosure of D1 in that D1 does not disclose

- a film containing both HPC and a fatty alcohol (see present claims 1-27);
- the production of a film by extrusion (see present claims 28-46).

This means that the special technical features under R. 13.2 PCT distinguishing INVENTION I and INVENTION II from D1 neither are the same nor do they correspond. There is also no indication that these two features contribute to the same technical problem.

For this reason, INVENTION I and INVENTION II lack unity of invention under R. 13 PCT.

**Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No  
**PCT/US2005/009203**

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees'**
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/55312 A (VIROTEX CORPORATION) 4 November 1999 (1999-11-04) page 14, lines 24-28; claims 1,17; examples 2,3,20,25,31,32,34,35,37	1-27
A	US 4 940 587 A (JENKINS ET AL) 10 July 1990 (1990-07-10) claims 1,5,8,17; examples 1-8	1-27
A	EP 0 250 187 A (JOHNSON & JOHNSON PRODUCTS INC; JOHNSON & JOHNSON CONSUMER PRODUCTS, I) 23 December 1987 (1987-12-23) claim 1	

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

# Patent Family Annex

Information on patent family members

International Application No

PCT/US2005/009203

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9955312	A	04-11-1999	AT 288743 T	15-02-2005
			AU 746339 B2	18-04-2002
			AU 3967899 A	16-11-1999
			CA 2329128 A1	04-11-1999
			DE 69923675 D1	17-03-2005
			DK 1079813 T3	06-06-2005
			EP 1079813 A2	07-03-2001
			JP 2002512950 T	08-05-2002
			WO 9955312 A2	04-11-1999
			US 2005048102 A1	03-03-2005
US 4940587	A	10-07-1990	AT 127687 T	15-09-1995
			AU 595801 B2	12-04-1990
			AU 5828486 A	18-12-1986
			CA 1277913 C	18-12-1990
			DE 3650390 D1	19-10-1995
			DE 3650390 T2	04-04-1996
			DK 273086 A	12-12-1986
			EP 0205282 A2	17-12-1986
			ES 8707110 A1	01-10-1987
			FI 862479 A ,B,	12-12-1986
			IL 78991 A	26-07-1990
			JP 2513999 B2	10-07-1996
			JP 61286321 A	16-12-1986
			KR 8902949 B1	14-08-1989
			NO 862287 A ,B,	12-12-1986
			PT 82746 A ,B	01-07-1986
			ZA 8604105 A	28-01-1987
EP 0250187	A	23-12-1987	US 4713243 A	15-12-1987
			AT 95058 T	15-10-1993
			AU 7415587 A	17-12-1987
			CA 1297408 C	17-03-1992
			DE 3787573 D1	04-11-1993
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			GR 870935 A1	19-10-1987
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			JP 2706064 B2	28-01-1998
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			JP 63019152 A	26-01-1988
			KR 9411243 B1	03-12-1994
			NZ 220573 A	28-11-1989
			PH 24845 A	30-10-1990
			SG 107694 G	28-10-1994
			US RE33093 E	17-10-1989
			ZA 8704294 A	25-01-1989